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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/576,839

04/20/2006

Roger Alberto

1621 WO/US

2298

7590

12/23/2008

Jerad Seurer  
Mallinckrodt Inc.  
675 McDonnell Boulevard  
P.O. Box 5840  
St. Louis, MO 63134

EXAMINER

JONES, DAMERON LEVEST

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

12/23/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/576,839	<b>Applicant(s)</b> ALBERTO ET AL.	
	<b>Examiner</b> D. L. Jones	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 34-53 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-51 and 53 is/are rejected.
- 7) ☒ Claim(s) 52 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/25/06</u> .   | 6) <input type="checkbox"/> Other: _____                          |

## **ACKNOWLEDGMENTS**

1. The Examiner acknowledges receipt of the amendment filed 4/20/06 wherein the specification was amended and claims 1-33 were canceled and claims 34-53 added.

**Note:** Claims 34-53 are pending.

## **APPLICANT'S INVENTIONS**

2. Applicant's invention is directed to method of treating cancer as set forth in independent claim 34. In addition, the instant invention has claims directed to compounds as set forth in independent claim 51.

## **112 SECOND PARAGRAPH REJECTIONS**

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 34, 37, 40, 45, 48, and 50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34-45 and 47-50: The claim as written is ambiguous because of the phrase 'the other one is optionally a monodentate ligand' (the phrase appears in independent claim 34). In particular, it is unclear what other definitions Applicant is assigning to the variables X1, X2, and X3 other than a monodentate ligand. Since claims 35-45 and 47-50 depend on claim 34 for its variable definitions, those claims are also vague and indefinite.

Claim 37: The claim is ambiguous because it is unclear what specific organic molecules having one of the integral groups Applicant is claiming that is compatible with instant invention.

Claim 40: The claim as written is ambiguous because it is unclear what organic groups containing a thioether function group or a terminal NC group that are compatible with the instant invention.

Claim 45: The claim is ambiguous because the definition of the phrase 'slight excess' will vary from person to person.

Claims 48 and 53: The claims as written are ambiguous because of the phrases 'analogues and derivatives'. In particular, it is unclear portion of the parent structure remains in the derivative/analog structure.

Claims 48 and 53: The phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim 50: The claim as written is ambiguous because of the term 'prodrug'. In particular, it is unclear what components make up Applicant's prodrug.

## **102 REJECTIONS**

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 51 is rejected under 35 U.S.C. 102(b) as being anticipated by Ardizzoia et al (European Journal of Inorganic Chemistry, 1998, Vol., 10, pages 1505-1512).

**Ardizzoia et al** disclose  $\text{Re}(\text{CO}_3)(\text{Hpz})_2\text{Br}$  which is the same as Compound 18 in claim 51. Thus, both Applicant and Ardizzoia et al disclose overlapping subject matter.

**Note:** *The search of independent claim 51 has not been extended beyond Compound 18 because prior art was found which could be used to reject the claim.*

7. Claims 34, 35, and 46-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith et al (Anticancer Research, 2003, Vol. 23, pages 63-70).

**Smith et al** disclose a gastrin the radiochemical investigations of an  $^{188}\text{Re}(\text{H}_2\text{O})(\text{CO})_3\text{-bombesin}$  conjugate. Since the GRP (gastrin) receptors are over expressed on a variety of cancer cells, a radiolabeled  $^{188}\text{Re}$ -bombesin analogue was desired (see entire document, especially, abstract; page 64, 'Materials and Methods'). In Scheme 1, page 65, the synthesis of  $^{188}\text{Re}(\text{H}_2\text{O})_3(\text{CO})_3^+$  is disclosed. On page 65 (first column, last paragraph), the biodistribution analysis of the  $^{188}\text{Re}(\text{H}_2\text{O})_3(\text{CO})_3\text{-bombesin}$  conjugate in tumor bearing mice is disclosed. Figures 2 and 3 (page 67) disclose the internalization analysis and efflux analysis of the radiolabeled complex. Tables I and II (page 68) disclose the biodistribution analysis of the radiolabeled complex comparing the result in normal subjects and those having a tumor. As a result of the in vitro and in vivo data of Smith et al, it was concluded that the new conjugate are possible cancer treatment materials (page 63, abstract). Thus, both Applicant and

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Smith et al disclose the use of a metal tricarbonyl compound as set forth in independent claim 34 in the treatment of cancer.

**Note:** *The search of independent claim 34 is allowable for Compound 18 because no prior art was found wherein the compound is used in treating cancer. Thus, the search was expanded to Compound 1. The search was not further expanded because prior art was cited which could be used to reject the claims.*

#### **CLAIM OBJECTION**

8. Claim 52 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Note:** It should be noted that for claim 51 the search has not been extended beyond Compound 18 in the instant invention.

#### **SPECIFICATION**

9. The disclosure is objected to because of the following informalities: the specification needs the heading 'Brief Description of the Drawings' on the top of page 11.

Appropriate correction is required.

#### **PRIORITY DOCUMENT**

10. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

**COMMENTS/NOTES**

11. It should be noted that the search of claim 51 has not been expanded beyond Compound 18 of the instant invention since prior art was found which could be used to reject the claims.

12. It should be noted that independent claim 34 is allowable for Compound 18 because no prior art was found wherein the compound is used in treating cancer. Thus, the search was expanded to Compound 1. The search was not further expanded because prior art was cited which could be used to reject the claims.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. - 3:15 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic

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Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. L. Jones/  
Primary Examiner  
Art Unit 1618

December 22, 2008